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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/514,626	06/23/2005	Finn Skou Pedersen	PEDERSEN10	7989

1444 7590 03/25/2008

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EXAMINER	
HORNING, MICHELLE S	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
03/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/514,626	PEDERSEN ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6-19,21,22,24,27-33,35-37,39 and 40* is/are pending in the application.

4a) Of the above claim(s) *11-19, 21-22, 24, 27-33, 35-37, 39-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 6-10* is/are rejected.

7)☒ Claim(s) *9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 November 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/23/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

This office action is responsive to communication filed 11/29/2007. The status of the claims is as follows: claims 1, 4, 6-19, 21, 22, 24, 27-33, 35-37, 39 and are pending of which claims 1, 4 and 6-10 are under current examination. Elected species are a purified retroviral env peptide of claims 1, 4 and 6-10 and the polypeptide of SEQ ID NO: 2 containing the R212M mutation.

Please note that this application has been transferred to another Examiner and all future correspondences regarding this application should be directed to Examiner Horning of AU 1648.

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 11/29/2007 is acknowledged.

Applicant's election with traverse of the species in the reply filed on 11/29/2007 is acknowledged. The traversal is on the ground(s) that it is not clear how species 1-3 are differentiated. In response, the differential species are drawn to distinct structures. The function of a protein is determined by its structure; each of the species will be different based on its structure and function.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 6/23/2005 was considered in its entirety.

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. The specification is not in compliance with the Sequence Rules. See, for examples, on pages 25 and 27.

The title of the invention, PURIFIED POLYPEPTIDE, ISOLATED NUCLEIC ACIDS ENCODING SAID POLYPEPTIDE, VECTORS AND USE THEREOF, is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See pages 6 and 21 for examples.

The disclosure is objected to because of the following informalities: Towers et al, 1999 is cited on page 5; however, this reference is not cited under References on page 44-45.

Appropriate correction is required.

The disclosure is objected to because of the following informalities: usage is spelled "usega".

Appropriate correction is required.

The abstract of the disclosure is objected to because usage is spelled "usega". Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 6 and 9 recite the limitation "said mutation" in claim 4. There is insufficient antecedent basis for this limitation in the claim. There is also no antecedent for "position 212" in claim 9.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Mark and Rapp (1984) as evidenced by Aagaard et al (2002) and Yang et al (1999).

Mark and Rapp describe the env sequences of Moloney-MCF, a pathogenic recombinant MuLV derived from a BALB/Mo (see Introduction). See Figure 7 for a comparison of the predicted amino acid sequence of the pCI-3, Mo-MCF and AKV ecotropic env genes. Note that all three sequences contain a glycine at site 212, in contrast to an arginine as found in wildtype SEQ ID NO: 2. The homologous site in the mutated SEQ ID NO: 2 contains a R212M. The following sequence analyses of the

Deleted: ***Claim Rejections - 35 USC § 103***¶
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:¶
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.¶
¶
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).¶
Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Towers et al (2000), Aagaard et al (2002) and US Patent 5858743 (hereinafter as "Russell").¶
Towers et al demonstrate a conserved mechanism of retrovirus restriction in a wide range of mammals, using the murine Fv1 gene which acts to restrict MLV replication (see whole document). The Fv1-sensitive viruses encode an ecotropic envelope and thus *only* infect rodent cells (see Abstract). The author[... [1]

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sequence of Figure 7 to that set forth in SEQ ID NO: 2 reveal a 94.2% homology. Note that SEQ ID NO:2 is the upper sequence.

```
Qy          1 MEGPAFSKPLKDKINPWGPLIVLGILMRARVSVQHDSPHQVFNVTWRVTNLMTGQTANAT
              ||||||||||||||||||||||:|||||:||  |||||||||||||||||||||||||||||
Db          1 MEGPAFSKPLKDKINPWGPLIILGILIRAGVSVQHDSPHQVFNVTWRVTNLMTGQTANAT

Qy         61 SLLGTMTDAFPKLYFDLCDLIGDDWDETGLGCRTPGGRKRARIFDFYVCPGHTVLAGCGG
              ||||||||||||||||||||:||||||||||||||||||||| ||||||||||  ||||
Db         61 SLLGTMTDAFPKLYFDLCDLVGDDWDETGLGCRTPGGRKRARTFDFYVCPGHTVPTGCGG
120

Qy        121 PREGYCGKWGCETTGQAYWKPSSSWDLISLKRGNTPKGQGPCYDSSVVSSSAQGATPGGR
              ||||||||||||||||||||||||||||||||||||||: |||||||  |||   :||||||
Db        121 PREGYCGKWGCETTGQAYWKPSSSWDLISLKRGNTPRNQGPCYDSSAVSSDIKGATPGGR
180

Qy        181 CNPLVLEFTDAGKRASWDASKAWGLRLYRSTMTDPVTRFSLTRQVLNIGPRVPIGPNPVI
              |||||||||||:|||| |||||||||||||||||||||||||||||||||||||||||||
Db        181 CNPLVLEFTDAGKRASWDGPKVWGLRLYRSTGTDPVTRFSLTRQVLNIGPRVPIGPNPVI
240

Qy        241 IDQLPPSRPVQIMLPRPPQPPPPGAASTVPETAPPSQQPGTGDRLLNLVNGAYQALNLTS
               |||||||||||||||||||||||| |||||||||| ||||||||||||||||||||||
Db        241 TDQLPPSRPVQIMLPRPPQPPPPGAASIVPETAPPSQQLGTGDRLLNLVNGAYQALNLTS
300

Qy        301 PDKTQECWLCLVAGPPYYEGVAVLGTYSNHTSAPANCSVASQHKLTLSEVTGQGLCVGAV
              |||||||||||||||||||||||||||||||||||||||||||| | |:|||: |
Db        301 PDKTQECWLCLVAGPPYYEGVAVLGTYSNHTSAPANCSVASQHKLTLSGVAGRGLCIAAF
360

Qy        361 PKTHQALCNTTQKTSNGSYYLAAPAGTIWACNTGLTPCLSTTVLDLTTDYCVLVELWPKV
              ||||||||||||||:|||:|||||||||||||||||||||||||||||||||||||||||
Db        361 PKTHQALCNTTQKTSDGSYHLAAPAGTIWACNTGLTPCLSTTVLDLTTDYCVLVELWPKV

Qy        421 TYHSPGYVYGQFE-EKTKYKREPVSLTLALLLGGLTMGGIAAGVGTGTTALVATQQFQQL
              ||||| ||||||  :|||||||||||||||||||||||||||||||||||||||||||||
Db        421 TYHSPSYVYGQFEKKKTKYKREPVSLTLALLLGGLTMGGIAAGVGTGTTALVATQQFQQL
480

Qy        480 QAAMQDDLKEVEKSITNLERSLTSLSEVVLQNRRGLDLLFLKEGGLCAALKEECCFYADH
              |||| ||||||||||||:|||||||||||||||||||||||||||||||||||||||||||
Db        481 QAAMHDDLKEVEKSITNLEKSLTSLSEVVLQNRRGLDLLFLKEGGLCAALKEECCFYADH
540

Qy        540 TGLVRDSMAKLRERLSQRQKLFESQQGWFEGLFNKSPWFTTLISTIMGPLIILLLILLFG
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        541 TGLVRDSMAKLRERLSQRQKLFESQQGWFEGLFNKSPWFTTLISTIMGPLIILLLILLFG
600

Qy        600 PCILNHLVQFIKDRVSVVQALVLTQQYHQLKTIEDCESRE 639
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                  | ||| |||||||:||||||||||||||||||| ||:|||
Db        601 PWILNRLVQPIKDRISVVQALVLTQQYHQLKTIGDCKSRE 640
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Aagaard et al, as discussed above, demonstrates which viruses lead to replication in the human cell line (U2OS) (see Figure 1). More specifically, the Moloney is capable infecting the human cell line. In contract, the AKV, for example, is not able to infect these cells but is capable of infecting BALB murine cells, demonstrating differential tropism. Yang et al discuss the receptors for polytropic and xenotropic viruses. Thus, the limitations of claims 4, 6 and 8 are met.

Claims 4, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Sijts et al (1994) as evidenced by Yang et al (1999).

Sijts et al clone the MCF1233 MLV and identify the sequences involved in viral tropism, oncogenicity and T cell epitope formation (see whole document). Figure 3 (page 346) provides a sequence alignment of the MCF1233 env protein with that of AKV, NCF247 and HOL. The sequence alignment that follows consists of the MCF1233 env protein sequence with the sequence set forth by SEQ ID NO: 2 of the instant application; analyses show a 94.6% homology between the two sequences with a glycine residue at the homologous site 212. Note that SEQ ID NO:2 is the upper sequence.

```
             1 MEGPAFSKPLKDKINPWGPLIVLGILMRARVSVQHDSPHQVFNVTWRVTNLMTGQTANAT 60
               |||||||||||||||||||||:||||:|| ||||||||||||||||||||||||||||||
Db           1 MEGPAFSKPLKDKINPWGPLIILGILIRAGVSVQHDSPHQVFNVTWRVTNLMTGQTANAT 60

Qy          61 SLLGTMTDAFPKLYFDLCDLIGDDWDETGLGCRTPGGRKRARIFDFYVCPGHTVLAGCGG
               |||||||||||||||||||||||||||||||||||||||||||||| ||||||||||  ||||
Db          61 SLLGTMTDAFPKLYFDLCDLIGDDWDETGLGCRTPGGRKRARTFDFYVCPGHTVPTGCGG
120

Qy         121 PREGYCGKWGCETTGQAYWKPSSSWDLISLKRGNTPKGQGPCYDSSVVSSSAQGATPGGR
               ||||||||||||||||||||||||||||||||||||||: |||||||| |||  :|||||||
```

Comment [BC1]: Huh? Why is it obvious to make the substitution at 212? Sounds like hindsight to say it was obvious that that substitution would change the tropism of the virus - unless that conclusion had already been made in the prior art. Also, position 212 of SEQ ID 2 is arg, not met. If your position is that the sequence in the prior art meets the limitations of the claims, then this should be a 102 - with secondary reference used as evidence re the tropism. As is written, it is not clear how primary reference differs from the claim and what motivation would be there to make the required changes.

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Claims 4, 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sijts et al (1994) in view of Yang et al (1999).¶

```
Db        121 PREGYCGKWGCETTGQAYWKPSSSWDLISLKRGNTPQNQGPCYDSSAVSSDIKGATPGGR
180

Qy        181 CNPLVLEFTDAGKRASWDASKAWGLRLYRST[M]TDPVTRFSLTRQVLNIGPRVPIGPNPVI
              ||||||||||||:|||| | ||||||| ||||||||||||:||||||||||||||||
Db        181 CNPLVLEFTDAGKKASWDGPKVWGLRLYRPT[G]TDPVTRFSLTRRVLNIGPRVPIGPNPVI
240

Qy        241 IDQLPPSRPVQIMLPRPPQPPPPGAASTVPETAPPSQQPGTGDRLLNLVNGAYQALNLTS
              ||||||||||||||||||||||||:| ||||||||||||||||||:||||||||||
Db        241 ADQLPPSRPVQIMLPRPPQPPPPGASSIVPETAPPSQQPGTGDRLLNLVDGAYQALNLTS
300

Qy        301 PDKTQECWLCLVAGPPYYEGVAVLGTYSNHTSAPANCSVASQHKLTLSEVTGQGLCVGAV
              |||||||||||||||||||||||||||||||| ||||||||||||||||||||||||
Db        301 PDKTQECWLCLVAGPPYYEGVAVLGTYSNHTSAPTNCSVASQHKLTLSEVTGQGLCVGAV
360

Qy        361 PKTHQALCNTTQKTSNGSYYLAAPAGTIWACNTGLTPCLSTTVLDLTTDYCVLVELWPKV
              ||||||||||||:|||||||||||||||||||||||||||||||||||||||||||||
Db        361 PKTHQALCNTTQKTSDGSYYLAAPAGTIWACNTGLTPCLSTTVLDLTTDYCVLVELWPKV
420

Qy        421 TYHSPGYVYGQFEEKTKYKREPVSLTLALLLGGLTMGGIAAGVGTGTTALVATQQFQQLQ
              |||||||| ||| ||||||||||||||||||||||||||||||||||||||||||||
Db        421 TYHSPGYVYDQFERKTKYKREPVSLTLALLLGGLTMGGIAAGVGTGTTALVATQQFQQLQ
480

Qy        481 AAMQDDLKEVEKSITNLERSLTSLSEVVLQNRRGLDLLFLKEGGLCAALKEECCFYADHT
              ||: :|||||||||||:|||||||||||||||||||||||||||||||||||||||||
Db        481 AAVHNDLKEVEKSITNLEKSLTSLSEVVLQNRRGLDLLFLKEGGLCAALKEECCFYADHT
540

Qy        541 GLVRDSMAKLRERLSQRQKLFESQQGWFEGLFNKSPWFTTLISTIMGPLIILLLLILFGP
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        541 GLVRDSMAKLRERLSQRQKLFESQQGWFEGLFNKSPWFTTLISTIMGPLIILLLLILFGP
600

Qy        601 CILNHLVQFIKDRVSVVQALVLTQQYHQLKTI--EDCESRE 639
              |||| |||||||:|||||||||||||||:|  |: ||||
Db        601 CILNRLVQFIKDRISVVQALVLTQQYHQLKSIDPEEVESRE 641
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Yang et al provides supportive teachings that human cells are permissive to MCF virus (see page 217); also described are the polytropic and xenotropic receptors for mice. Thus, the limitations of 4, 6 and 8 are met by the prior art.

Comment [BC2]: Again, where is the motivation to make the substitution at 212? This could also be 102 or 102/103.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Towers et al (2000), Aagaard et al (2002) and US Patent 5858743 (hereinafter as "Russell").

Towers et al demonstrate a conserved mechanism of retrovirus restriction in a wide range of mammals, using the murine Fv1 gene which acts to restrict MLV replication (see whole document). The Fv1-sensitive viruses encode an ecotropic envelope and thus *only* infect rodent cells (see Abstract). The authors provide that the Fv1-like retrovirus restriction function is directed at amino acid 110 of the viral capsid protein and a substitution of arginine for glutamate allowed infection of human cells (see

Results, page 12296). Figure 1 depicts Fv1-like restriction to N-tropic virus infection in nonmurine cells, including those of dog, pig, cow and human. The authors state that all of the cells showing $Fv1^b$-like restriction were infected by the 110 mutant (see page 12296). This reference does not provide any teaching with respect to a purified env protein.

Aagaard et al is discussed in further support of the teachings by Towers et al. The authors "present data that support and strengthen the existence of Fv1-like restriction in human cells" as taught by Towers et al using the full-length genome virus (see page 439). Using mCAT-1-expressing human cells, the authors show that N-tropic MLVs are restricted in both infection and replication and B-tropic viruses with a modification at site 110 escape restriction. Figure 1 demonstrates the replication efficiency of multiple viruses in murine and human cells. Specifically, the human cells failed to reveal virus production to two viruses, Akv and SL3-3, as quantified by reverse transcriptase assay.

Russell et al provide an invention in which the tropism of a MLV env particle is altered by fusing a surface exposed EFG particle to the env protein (see whole document). They state that a "particle comprising an MLV-env protein that binds to an MLV-env receptor on the surface of a target cell so as to cause infection thereof". Paragraph 6 recites: "Retroviral envelope glycoproteins mediate specific viral attachment to cell surface receptors and subsequently trigger fusion between the viral envelope and the target cell membrane. Retroviral envelope glycoproteins consist

of an external glycoprotein moiety (SU) noncovalently attached at its C-terminus to a smaller transmembrane polypeptide moiety (TM)." And paragraph 8 states: "Moloney MLV is an ecotropic virus whose envelope attaches to mouse and rat cells but not to human cells."

Thus, the following are provided by the prior art: 1. MLV demonstrates restriction in both infection and replication, 2. Akv and SL3-3 fail to infect human cells in their wildtype form (without modification of structure) and 3. MLV env proteins attach to specific receptors leading to infection. While the claim is specific to the viral infection by way of receptors in the NIH Swiss inbred NFS/N mouse and not by way of the human receptors encoded by RMC1 locus, note that the above teachings discuss restriction of infection among mammals and such viral infections include that by Moloney MLV and Akv and SL3-3 are shown to either to fail to attach to human cells or produce virus in human cells. Given the known teachings, it would have been obvious to produce an envelope polypeptide from the SL3-3, which is capable of infecting a mouse cell and not a human cell. One would have been motivated to do so because for structural manipulations leading to cell retargeting (as taught by Russell). There would have been a reasonable expectation of success, given the prior art provides much detail in characterizing the MLV virus, including its infection and replication process. Further, the underlying techniques are commonly used by the skilled artisan. The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 7 and 10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over either one of Sijts et al (1994) or Mark and Rapp (1984).

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As discussed above, the teachings of Sijts et al and Mark and Rapp meet the structural limitations of the env protein in claim 4. However, it cannot be determined by examination whether the structure's tropism can be altered following one substitution or if the structure is capable of mediating a higher infectivity in human cells than other viruses, specifically, MCF-247, MCF-13 and X-MLV. While it is known to the ordinary artisan that there exists a correlation of structure to function of a protein, such that, a change in structure (i.e. a substitution) leads to a change in function, the Office has no laboratory to ascertain whether a change in function will lead to altered tropism. Further, the function of a protein is inherent to its structure. See MPEP 2112.

Allowable Matter

Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michelle Horning/
Examiner, Art Unit 1648

/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648